

JAN 14 1999

EXHIBIT 3

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K984172

Contact: Paul V. Holmes *MSc, PhD, DrMedSc.*, General Manager

November 18, 1998

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
Proprietary-Trade Name: *PureSperm*[®]
Classification Name/Product Code: Procode: 85 MQL CFR#: 884.6180
Common/Usual Name: Sperm Separation Medium
2. Equivalent legally marketed devices: *PureSperm*[®] K980814
3. Indications for Use (intended use) The product is intended to be used for the separation and purification of spermatozoa by density gradient centrifugation of human semen samples, where the prepared sperm are used for the treatment of involuntary infertility by utilizing one of the Assisted Reproductive Technologies (ART).
4. Description of the Device: The product *PureSperm*[®] is based on a buffered salt solution which contains a colloidal suspension of silica particles, with hydrophilic silane covalently bound to the particles. The pH, osmolality and salts of *PureSperm*[®] are formulated to be compatible with human sperm during their centrifugal separation and purification. The product is packaged in three bottle sizes, 100, 250 and 1000 mL, and these bottles, being Type I borosilicate glass, are packaged individually in white virgin-fibre cartons. Both the bottles and the cartons have pharmaceutically approved labels showing batch number, production date and expiration date. In addition, every carton contains an insert with a full description of the product, including instructions for use and precautions.
5. Safety and Effectiveness, comparison to predicate devices. The results of clinical trials and comparative testing against predicate products indicates that the new device is as safe and effective as the predicate devices.
6. Conclusion: Based on the identical composition, product testing results, and intended use, *PureSperm*[®] is substantially equivalent to the predicate device named above.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Daniel Kamm, P.E.
Regulatory Engineer
Kamm and Associates
P.O. Box 7007
Deerfield, IL 60015Re: K984172
PureSperm®
Dated: November 6, 1998
Received: November 20, 1998
Regulatory Class: II
21CFR 884.6180/Procode: 85 MQL

Dear Mr. Kamm:

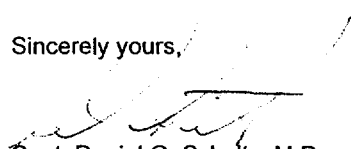
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K984172

Device Name: *PureSperm*[®] Sperm separation medium, Density gradient centrifugation medium

Indications for Use: The product is intended to be used for the separation and purification of spermatozoa by density gradient centrifugation of human semen samples, where the prepared sperm are used for the treatment of involuntary infertility by utilizing one of the Assisted Reproductive Technologies (ART).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____

(Per 21 CFR 801.109)

David M. Begeman
(Division S...
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K984172